Remarks

Amendments to the Claims

Claims 1-46 were pending in this application, and subject to a Restriction Requirement. New claims 47-48 are added herein. Support for new claims 47-48 can be found throughout the specification, for example on page 24, line 8 to page 25, line 28, and on page 26, lines 25-32.

Applicants believe no new matter is introduced by these amendments. To the extent that any of the claims are viewed to be narrowed by the amendments made herein, Applicants reserve the right to pursue protection of the broader scope of the subject matter in this or a later-filed application.

After entry of this amendment, **Claims 1-48 are pending in the application.** Consideration of the pending claims is requested.

Restriction Requirement

In response to the restriction requirement, Applicants provisionally elect, with traverse, the claims of Group I, directed to a polypeptide, compositions including the polypeptide, and methods for producing an immune response using the polypeptide (claims 1-5, 26-30, and 39), with traverse.

The Office action alleges that the pending claims describe eleven different inventions or groups of inventions (I through XI) which are not so linked as to form a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical feature. However, Applicants submit that the pending claims satisfy the requirement of Rule 13^{bis}, and should be examined together.

Applicants specifically respectfully request that the subject matter of Group I (polypeptides and their use to treat tumors) be rejoined with the subject matter of Group II (polynucleotides). The present application discloses SV-NGEP, immunogenic fragments thereof, nucleic acids encoding SV-NGEP and fragments thereof, and methods of use. This application is a U.S. national phase application which entered the national phase under § 371; the PCT guidelines related to unity of invention apply. These guidelines are set forth, for example,

in M.P.E.P § 1850, which states that "examples concerning Unity of Invention involving biotechnological inventions may be found in Chapter 10 of the International Search and Preliminary Examination Guidelines which can be obtained from WIPO's web site (www.wip.int.pct/en/texts/gdlines.htm).

For the Examiner's convenience, a copy of page 96 from Chapter 10 is attached as Exhibit A (see Example 39, Protein and its Encoding DNA). As disclosed in Chapter 10 of the PCT guidelines, if there is no prior art that teaches the claimed protein or nucleic acid sequence, and the claimed DNA encodes protein X (in the present application, PAGE-4), then the claims to the protein and the nucleic acid should be examined in a single application. Specifically, because the protein makes a contribution over the prior art, the protein and the DNA share a corresponding technical feature, and the claims have unity of invention (*a priori*). In the present application, Applicants submit that, because the amino acid sequence of SV-NGEP is novel and non-obvious over the prior art, there is clearly unity of invention between the SV-NGEP proteins and nucleic acid encoding these proteins.

A description of the PTO's agreement with the PCT guidelines on Unity of Invention can be found in Special Program Examiner Julie Burke's presentation entitled "Unity of Invention, Biotech Practice," which is available from the U.S. Patent and Trademark Office. For the Examiner's convenience, a copy of a slide illustrating unity of invention for disclosures including proteins and DNA is attached as Exhibit B.

Applicants note that all of the claims were examined during International prosecution, and were determined to be novel over the prior art of record. In view of the PCT guidelines, the U.S. PTO presentation, and the previous search by the European Patent Office during international prosecution, reconsideration and rejoinder of Group I with Group II is respectfully requested.

Applicants thank the Examiner for noting that a restriction has been required between product and process claims, and for confirming that if a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. In addition, process claims that depend from or otherwise include all of the limitations of the patentable product will be entered as a matter of right if presented prior to final rejection or allowance, whichever is earlier.

Conclusion

It is respectfully submitted that the amended claims submitted herewith should all be recombined and considered in the current case, and as such they are in a condition for substantive examination. Applicants respectfully request examination of Groups I and II. In the unlikely event that the restriction requirement is maintained, Applicants elect Group I, with traverse. If an additional restriction requirement is asserted, or if the present restriction requirement is maintained in its present form, the Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview, as it is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

Respectfully submitted,

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By _____
Susan Alpert Siegel, Ph.D.
Registration No. 43,121

One possible grouping would be:

Invention 1: Method to identify compounds... (claim 1)

Invention 2: Compound X (claim 2)

Invention 3: Compound Y (claim 3)

Invention 4: Compound Z (claim 4)

10.59 *Example 39: Protein and its Encoding DNA*

Claim 1: Isolated protein X having SEQ ID NO: 1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1.

(Some Authorities presume that a claimed biological molecule is in isolated form and therefore do not require the claim to explicitly include the term "isolated" as above.)

The disclosure teaches that protein X is an interleukin-1, a soluble cytokine involved in the activation of lymphocytes. The disclosure also sets forth a DNA molecule having SEQ ID NO: 2 that encodes SEQ ID NO: 1.

There is no prior art.

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*).

Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

If an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X, some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity. Examples of such a claim follow:

Isolated DNA molecule encoding protein X, or a DNA fragment thereof.

Isolated DNA molecule having SEQ ID NO: 2, or DNA molecules which hybridise to SEQ ID NO: 2 under stringent conditions.

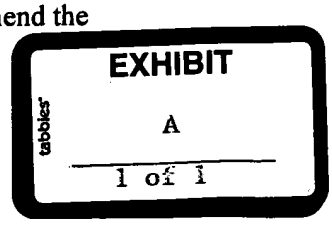
If prior art existed teaching either protein X or the DNA encoding protein X, some Authorities might find that the same or corresponding technical feature did not make a contribution over the prior art, that is, was not a special technical feature, and therefore unity was lacking (*a posteriori*).

Process at the International Search Stage

Invitation to Pay Additional Fees

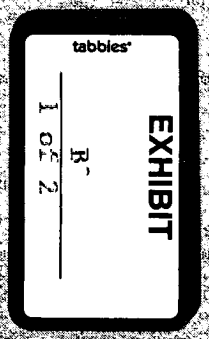
Article 17(3)(a); Rules 16, 40.2, 40.3, 42

10.60 After deciding that lack of unity exists, except in the circumstances described in paragraphs 10.64 and 10.65, the International Searching Authority informs the applicant of the lack of unity of invention by a communication, preceding (but see paragraph 10.61, below) the issuance of the international search report and written opinion of the International Searching Authority, which contains an invitation to pay additional fees (Form PCT/ISA/206). This invitation specifies the reasons (see paragraph 10.63) for which the international application is not considered as complying with the requirement of unity of invention, identifies the separate inventions and indicates the number of additional search fees and the amount to be paid. The International Searching Authority cannot consider the application withdrawn for lack of unity of invention, nor invite the applicant to amend the



Unity of Invention Biotechnology Practice

Julie Burke
USPTO TC1600
Special Program Examiner



Example 17; Annex B of the Administrative Instructions

Scenario A

Claim 1. Isolated Protein X.
Claim 2. Isolated DNA encoding Protein X.

Wherein Protein X and DNA are a contribution over the prior art?

Scenario B

Claim 1. Isolated Protein X.
Claim 2. Isolated DNA encoding Protein X.

Wherein DNA or Protein X are NOT a contribution over the prior art?
Do the DNA and protein share a special technical feature?